

REMARKS

Claim Rejections 35 U.S.C. § 103

The Examiner has rejected pending Claims 1, 3, 9 and 11 under 35 USC §103(a) as being unpatentable over Kamiya et al. (USPN 5,192,309) in view of Kensey et al. (USPN 5,676,689.) The Examiner contends that the Kamiya reference discloses a locator device having an elongate member with a distal opening “(portion of 27 adjacent lumen 24),” a proximal opening (through which the guidewire is inserted) and an expandable occlusion member (21) in contact with the lumen of the elongate member and located distally of the distal opening of the elongate member. The Examiner acknowledges that Kamiya et al. fails to disclose the use of a bioabsorbable material, but cites the Kensey reference to supply this missing teaching. With regards to the Kamiya reference, the Examiner states “the elongate member and occlusion member are capable of performing the functions as claimed.” Applicant respectfully disagrees with this interpretation of the Kamiya reference for the reasons discussed below.

First, independent claim 1 positively requires that the elongate member be “adapted to extend into a blood vessel of a patient such that said distal opening is located in the lumen of the blood vessel.” Independent claim 9 has a corresponding limitation. Both require that the elongate member be configured so that the distal opening can be positioned within the patient’s blood vessel.

In contrast, one of skill in the art would immediately recognize that element 27 of the Kamiya reference is a conventional catheter side arm that allows fluids to be introduced to or withdrawn from the lumen of the catheter while the distal end is positioned within the patient. As such, element 27 is designed to remain outside the body of the patient. Although the Kamiya et al. reference does not specifically identify element 27 in the specification, it does describe the operation of the device with respect to corresponding structure 15 from Fig. 26 as follows: “physiological saline at a temperature of 45°C is injected to the catheter 12 through the inlet 15, and the flange is recovered to the original shape and thus the closing plug is tightly fixed to the defect to close it.” Thus, it is apparent that element 15, and likewise element 27, are intended to

function as conventional catheter side arms and are not intended to be inserted into a patient's body.

Furthermore, one of skill in the art would appreciate that the claim limitation that the elongate member be "adapted to extend into a blood vessel of a patient such that said distal opening is located in the lumen of the blood vessel" indicates specific, structural features. It must be shaped to fit within a blood vessel and it must be designed to be inserted within the blood vessel, for example by using a conventional introducer. Element 27 does not exhibit any characteristics that make it adapted to extend into a blood vessel. Element 27 extends out from the longitudinal profile of elongate member 22, making it likely to cause injury to a blood vessel if it were inserted within. Further, its angle would cause it to act like the barb of a fish hook, impeding removal of the elongated member from the vessel. Also, its configuration would require an introducer capable of passing it to make a much larger penetration into the patient's body than necessary.

Finally, even if it were possible to position element 27 within a patient's blood vessel, applicant respectfully submits that this would represent a modification of the Kamiya reference that would render it unsuitable for its intended purpose. The Kamiya reference describes the operation of the device shown in Fig. 27 as follows: "The temperature of the closing plug can be accurately controlled by passing physiological saline at a temperature of, for example, 25°C through the catheter 22 and thus the unfavorable recovery of the original shape during the insertion is securely prevented. From the description of inlet 15 discussed above, it is clear that the Kamiya reference is relying on element 27 for the introduction of saline to control the temperature of the shape memory closing plug. If element 27 were positioned within the blood vessel in the manner suggested by the Examiner, the operation described by Kamiya et al. would not be possible. As explained in MPEP 2143.01, section V, it is improper to suggest a modification that would render the prior art unsuitable for its intended purpose.

For the above reasons, applicant respectfully submits that the Kamiya et al. reference does not disclose an elongated member having a distal opening adapted to extend into a blood vessel of a patient such that the distal opening is located in the lumen of the blood vessel. Further, since the Kensey reference is cited only for its suggestion of using bioabsorbable materials, it does not

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compensate for this deficiency. Accordingly, the combination of Kamiya et al. and Kensey et al. does not suggest the invention as claimed. Therefore, applicant respectfully requests that Examiner reconsider and withdraw the § 103 rejection of pending Claims 1, 3, 9 and 11. Also, as discussed in the previous response, Applicant requests that method Claims 5 and 7 be rejoined, as they share all the limitations of the product claims discussed above.


Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

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